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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,585	11/27/2001	Douglas Levinson	10436-0015-999	7294

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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,585

Applicant(s)

LEVINSON, DOUGLAS

Examiner

Jon D Epperson

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-28, 35, 45 and 51-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34, 36-44 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10 6) ☐ Other:

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on September 12, 2003 (Paper No. 9).

Priority Claims

2. The priority filing date of November 28, 2000 is acknowledged for Provisional Application 60/253,629.

Status of the Claims

3. Claims 1-80 were pending in the present application.
4. Applicant's response to the Restriction and/or Election of Species requirements in Paper Nos. 5 and 9 is acknowledged (Applicant elected with traverse Group III, claims 29-50) and claims 1-28 and 51-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see below i.e., Response to Restriction and/or Election of Species).

Art Unit: 1639

5. Please note: Applicant's elected species (see Paper Nos. 5 and 9) were found in the art, see rejections below. Applicant is reminded of MPEP § 803.02 with respect to species elections:

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. *The prior art search, however, will not be extended unnecessarily to cover all nonelected species.* Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

6. Claims 35 and 45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species, the requirement having been traversed in Paper Nos. 5 and 9 (see below i.e., *Response to Restriction and/or Election of Species*).

7. Therefore, claims 29-34, 36-44 and 46-50 are examined on the merits in this action.

Response to Restriction and/or Election of Species

8. Applicant's election of Group III (i.e., claims 29-50) **with traverse** in Paper Nos. 5 and 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)).

Art Unit: 1639

9. Applicant's election of species in Paper Nos. 5 and 9 is also acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)).

10. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

11. The information disclosure statement filed September 12, 2003, fails, in part, to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because one publication cited therein, numbered R14, lack a publication date, a necessary element for consideration. Applicant is advised that the date of any re-submission of this citation contained in this information disclosure statement or the submission of the missing element – the publication date – will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

Specification

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Objections to the Claims

14. Claim(s) 1 is/are objected to because of the following informalities:

A. Claims 46-47 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 36-37. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 29-34, 36-44 and 46-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 29-34, 36-44 and 46-50 are rejected because the “disease-causing substance” in these claims is not defined with any chemical or physical characteristic, but only by functional properties (section 5.1.2 of the specification does not cure this deficiency). A claim to a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed

Art Unit: 1639

invention. A person of skill in the art cannot immediately envision all the possible chemical structures for a compound with this function i.e., ability to cause a disease. Thus, the metes and bounds of the claimed invention cannot be determined. See *ex parte Pulvari* (POBA 1966) 157 USPQ 169.

B. **Claim 40** recites improper Markush format. For example, claim 40 reads “disease-causing substance is calcium phosphate, ... protein structure, or a protein precipitate or a hydrate or a mixture thereof.” The term “or” must only be used only once. It is suggested to use standard Markush language; see MPEP

2173.05(h) concerning alternative expressions:

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being “selected from the group consisting of A, B and C.” See *Ex parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1925).

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if “wherein R is a material selected from the group consisting of A, B, C and D” is a proper limitation, then “wherein R is A, B, C or D” shall also be considered proper.

Therefore, claims 40 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

16. Claims 29-34, 36-44 and 46-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson et al (WO 01/51919).

For *claim 29*, Levinson et al (see entire document) disclose method steps for the high-throughput formation, identification, and analysis of diverse solid-forms (see Levinson et al, abstract), which anticipates claim 29. For example, Levinson et al disclose screening an array of at least 24 samples (e.g., see Levinson et al, page 10, lines 15-31; see also claims 22, 39, 60, 104, 118, 128, 141 and 153 wherein "at least 24" samples are disclosed). Levinson et al further disclose screening this array to identify conditions, compounds, or compositions that inhibit prevent induce, modify or reverse transitions of physical state (e.g., see Levinson et al, claims 26(b)/(e), 43(b)/(e), 65(b)/(e), 91(b)/(e), 108(d) and 132(d) showing one or more of the samples differ in their "physical state"; see also page 29, line 15 disclosing "inhibitors of polymorphic shift" i.e., inhibitors of transition of physical state; see especially page 13, lines 25-29, "Each sample ... in the array can be subjected to ... induce, inhibit, prevent, or reverse formation of solid-forms [i.e., transitions of physical state] of the compound-of-interest"). Furthermore, Levinson et al disclose the addition of "disease-causing" substances

like calcium phosphate (e.g., see Levinson et al, page 24, line 27; see also page 25, line 9 wherein Levinson et al disclose cholesterol; see also page 65, line 29 wherein Levinson et al disclose the screening of “amyloid formation”, presumably for Alzheimer’s disease wherein the physical state is “induced”); see also page 45, lines 6-8), which falls within the “disease-causing” substances disclosed by Applicants in claim 40 (i.e., compare to claim 40 of current application). Finally, Levinson et al disclose “analyzing” the array (e.g., see Levinson et al, claims 39(c), 46-47, 60(b), 104(c); see also figure 1).

For *claim 30*, Levinson et al disclose solids, liquids and dissolved forms (e.g., see Levinson et al, page 33, section 4.8 on physical states).

For *claim 31*, Levinson et al disclose liquid medium (e.g., see page 8, line 23 wherein Levinson et al disclose gastric fluid).

For *claim 32*, Levinson et al disclose, “adding a component” (e.g., see claims 28(f), 50(f), 75(c), 92(f), 109(f)).

For *claims 33-34*, Levinson et al disclose both small and large components (e.g., see page 23, lines 22-23; see also page 43, lines 20-21).

For *claims 36 and 46*, Levinson et al disclose at least 48 samples (e.g., see claims 81, 166).

For *claims 37 and 47*, Levinson et al disclose at least 96 samples (e.g., see claims 82, 167).

For *claims 38-39*, Levinson et al disclose the samples differ, for example, by “identity” (e.g., see claims 26(c), 43(c), 65(c), 91(c), 108(b), 132(b)).

For *claim 40*, Levinson et al disclose the addition of “disease-causing” substances like calcium phosphate, cholesterol and amyloid (e.g., see Levinson et al, page 24, line 27; see also page 25, line 9 wherein Levinson et al disclose cholesterol; see also page 65, line 29 wherein Levinson et al disclose the screening of “amyloid formation” i.e., physical state is “induced”; see also page 45, lines 6-8).

For *claim 41*, Levinson et al disclose that the method “is directed to methods and systems for rapidly producing and screening large numbers of samples to detect the presence or absence of solid-forms” (e.g., see Levinson et al, page 1, line 14; see also page 14, line 4).

For *claim 42*, Levinson et al disclose polarized light analysis (e.g., see Levinson et al, claim 45).

For *claim 43*, Levinson et al disclose determining if the solid is amorphous or crystalline (e.g., see Levinson et al, claim 44).

For *claim 44*, Levinson et al disclose Raman spectroscopy (e.g., see Levinson et al, claims 46, 70, 126).

For *claims 48-50*, Levinson et al disclose screening hundreds of thousands of samples per day (e.g., see Levinson et al, page 7, lines 25-26; page 8, lines 3-4).

17. Claims 29-34 and 36-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Hol et al (U.S. Patent No. 6,267,935).

For *claim 29*, Hol et al (see entire document) disclose a method useful in the crystallization of proteins and other molecules (see Hol et al, abstract), which anticipates claim 29. For example, Hol et al disclose screening plates with a plurality of reservoirs and four sets of 48 different crystallization solutions (e.g., see Hol et al, figure 1 and Tables 1-4). Hol et al further disclosing screening this array to identify conditions, compounds, or compositions that inhibit prevent induce, modify or reverse transitions of physical state (e.g., see Hol et al, column 3, lines 3-11, "a large number of crystallization conditions [can] be easily and simultaneously tested [i.e., screened] in order to identify conditions under which a target molecule ... can be crystallized [i.e., an induced physical transition]"). Furthermore, Hol et al disclose the addition of "disease-causing" substances like proteins (e.g., see Hol et al, column 1, line 15; see also column 11, lines 55-65). Hol et al does not explicitly state that the proteins are "disease causing", but proteins would fall within the list of disease causing substances disclosed by Applicants in claim 40 (i.e., the "protein-structure"). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Finally, Hol et al disclose "analyzing" the array (e.g., see Hol et al, column 11, lines 8-20).

For *claims 30-31*, Hol et al disclose solid and liquid (e.g., see Hol et al, column 1, line 37; see also column 10, lines 35-55).

For *claim 32-34*, Hol et al disclose "an additive" (e.g., see Hol et al, abstract; see also column 2, line 10; see also Tables 1-4 that lists specific examples).

For *claims 36-37 and 46-47*, Hol et al disclose four sets of 48 different crystallization solutions i.e., $4 \times 48 = 192$ (e.g., Hol et al, column 2, paragraph 2; see also Figure 1; see also Tables 1-4).

For *claims 38-39*, Hol et al disclose the samples differ, for example, by "pH" or "identity or amount of one of the components" (e.g., see Tables 1-4).

For *claim 40*, Hol et al disclose the addition of "disease-causing" substances like proteins (e.g., see Hol et al, column 1, line 15; see also column 11, lines 55-65). Hol et al does not explicitly state that the proteins are "disease causing", but proteins would fall within the list of disease causing substances disclosed by Applicants in claim 40 (i.e., the "protein-structure"). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For *claim 41*, Hol et al disclose the detection of solid (e.g., see Hol et al, column 11, line 12).

For *claim 42*, Hol et al disclose visual inspection and/or microscopy (e.g., see Hol et al, column 11, lines 8-20).

For *claim 43*, Hol et al disclose determining if the solid is amorphous or crystalline (e.g., see Hol et al, column 11, line 12).

For *claim 44*, Hol et al disclose X-ray diffraction (e.g., see Hol et al, column 11, lines 40-44).

18. Claims 29-34, 36-44 and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Leskovar et al (Leskovar, P.; Vogel, E.; Rozehnal, A. "A direct comparison of the litholytic capacity of renacidin and some new calcium oxalate and/or phosphate dissolving irrigation systems" Urolithiasis Relat. Clin. Res., [Proc. Int. Symp.] 5th (1985), Meeting Date **1984**, 627-30.).

For *claim 29*, Leskovar et al (see entire document) disclose methods for dissolving struvite, calcium oxalate and apatite calculi (see Leskovar et al, Introduction), which anticipates claim 29. For example, Leskovar et al disclose forming an array of "1000 single calculi" that were subdivided according to their "composition" and "size" for testing against "44" single and combined irrigation systems (e.g., see Leskovar et al, paragraph bridging pages 627-628; see also Tables 1-5). Leskovar et al further disclosing screening this array to identify conditions, compounds, or compositions that inhibit prevent induce, modify or

reverse transitions of physical state (e.g., see Leskovar et al, Table 1 showing dissolution of calcium oxalate calculi by test solutions). Here, the “disease causing” substance is “calcium oxalate” (e.g., see Leskovar et al, Table 1). Finally, Leskovar et al disclose “analyzing” the array members via X-ray diffraction and/or gravimetric analysis (e.g., see Leskovar et al, paragraph bridging pages 627-628; see also Tables 1-5).

For *claims 30-31*, Leskovar et al disclose solid and dissolved forms (e.g., see Leskovar et al, Table 1 showing % dissolution of calcium oxalate). Leskovar et al also disclose various “test solutions” i.e., medium (e.g., see Leskovar et al, Table 1, Test solutions).

For *claim 32-34*, Leskovar et al disclose “an additive” (e.g., see Leskovar et al, Table 1 showing various “components” in test solutions including both “large” and “small” molecules).

For *claims 36-37 and 46-47*, Leskovar et al disclose tests on 1000 single calculi using 44 single and combined irrigation systems (e.g., Leskovar et al, paragraph bridging pages 627-628; see also Tables 1-5).

For *claims 38-39*, Leskovar et al disclose the samples differ, for example, by “pH” or “concentration” and “identity” of components (e.g., see Leskovar et al, paragraph bridging pages 627-628, Tables 1-5).

For *claim 40*, Leskovar et al disclose the addition of “disease-causing” calcium oxalate i.e., Applicant’s elected species (see Leskovar et al, Introduction; see also Tables 1).

For *claim 41*, Leskovar et al disclose the detection of dissolution of a solid (e.g., see Leskovar et al, Introduction; see also Table 1).

For *claim 42*, Leskovar et al disclose visual inspection (e.g., see Leskovar et al, paragraph bridging pages 627-628).

For *claim 43*, Leskovar et al disclose determining if the solid is amorphous or crystalline (e.g., see Leskovar et al, paragraph bridging pages 627-628).

For *claim 44*, Leskovar et al disclose X-ray diffraction (e.g., see Leskovar et al, paragraph bridging pages 627-628).

For *claims 46-49*, Leskovar et al disclose screening 1000 samples/day (e.g., see Leskovar et al, page 627, last paragraph; see also Tables 1-5).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
November 25, 2003

BENNETT GELSA
PRIMARY EXAMINER



Art Unit: 1639